# This Page Is Inserted by IFW Operations and is not a part of the Official Record

### BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

1 Publication number:

0116220

**B1** 

(12)

#### **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication of patent specification: 09.08.89

(i) Int. Cl.4: A 61 B 17/12

(1) Application number: 83307661.5

(2) Date of filing: 16.12.83

(A) Surgical instrument for applying clips to a surgical site.

- (3) Priority: 06.01.83 US 456163
- 4 Date of publication of application: 22.08.84 Bulletin 84/34
- (4) Publication of the grant of the patent: 09.08.89 Bulletin 89/32
- (A) Designated Contracting States:
  AT BE CH DE FR GB IT LI LU NL SE
- (3) References cited: GB-A-2 044 108 US-A-2 194 748 US-A-4 296 751

- (7) Proprietor: BAXTER INTERNATIONAL INC. (a Delaware corporation)
  One Baxter Parkway
  Deerfield Illinois 60015 (US)
- Inventor: Blake, Joseph Walter, III. 88 Main Street New Canaan Connecticut (US) Inventor: Di Cesare, Paul Charles 88 Main Street New Canaan Connecticut (US)
- (A) Representative: Seaborn, George Stephen et al c/o Edward Evans & Co. Chancery House 53-64 Chancery Lane London WC2A 1SD (GB)

P 0116220 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European patent convention).

20

25

30

35

50

55

The present invention relates to a surgical instrument. More particularly, the invention relates to a ligating instrument. Still more specifically, this invention relates to a clip-dispensing and applying ligating device.

Surgical instruments of the type here under discussion are known in a variety of structural designs. For example, it is known to provide hemostatic forceps which are individually loaded with securing clips; among such clip applicators is that disclosed in U.S. Patent No. 3,777,538, the jaws of which can be incrementally rotated about a longitudinal axis. GB-A-2 044 108 discloses a surgical instrument for applying clips to a surgical site, comprising applicator means having a pair of cooperating jaws which are movable between an open and a closed position to cinch a clip located therebetween upon closure of the jaws and mounting means on which are mounted the jaws for angular displacement so as to vary the orientation at which the clip is presented to a surgical site. The instrument is capable of single hand actuation of the jaws and the angular displacement. The instrument has no supply means for feeding clips to the jaws.

It has also been proposed to utilize a magazineloaded hemostatic forceps with semiautomatic clip feed and, in fact, other proposals involve the use of magazine-loaded devices with automatic clip feed.

Some of these devices are too complicated and/ or difficult to use and have therefore never found any acceptance. Others work more or less well and have found acceptance in the medical profession to a greater or lesser degree.

All of the prior art instruments of the type in question and provided with means for feeding clips to be applied to a surgical site have one thing in common, however; there is no way to change the presentation of the leading clip to a surgical site, i.e., its orientation relative to the site, unless the user (surgeon) changes the position of his hand in which he holds the instrument. This may, at first mention, appear to be a relatively minor matter; in point of fact, however, since much depends upon the ease and absence of fatigue with which the surgeon is able to hold his hand, it is not a minor point. Thus, should he be forced to hold his hand in a position which to him is fatiguing, he may rapidly reach the point at which his hand is no longer steady enough to apply the clips with the necessary precision.

Stapling devices are known for externally stapling or suturing the skin. In known such devices, disclosed, for example, in U.S. Patent Nos. 3,819,100 (Reissue 28,932), 3,949,924, 4,196,836 and 4,204,623, it is possible to rotate the staple housing about a longitudinal axis. In these devices, however, rotation of the staple housing to any degree is not readily possible by manipulation with the same hand which actuates the stapling operation. Although such stapling devices are known, no one heretofore had con-

sidered rotating the clip housing in ligating devices using openable and closable jaws.

Accordingly, it is a general object of the present invention to overcome the disadvantages of the prior art.

A more particular object of the invention is to provide an improved surgical clip-applying instrument which is not possessed of the aforementioned prior-art disadvantages.

Another object of the invention is to provide a surgical instrument of the type under discussion which permits variations in the presentation (orientation) of at least the leading clip of a string of clips relative to a surgical site without requiring concomitant change in the orientation of a user's hand holding the instrument.

Still a further object of the present invention is to provide such an instrument as outlined hereinbefore which is of relatively simple construction and therefore comparatively inexpensive and disposable.

Yet another object is to provide such an instrument which is reliable and which in use comes as close as possible to being free of malfunctions.

In keeping with these objects, and with still others which will become apparent hereinafter, the invention provides a surgical instrument for applying clips to a surgical site, comprising applicator means having a pair of cooperating jaws which are movable between an open and a closed position; supply means for feeding surgical clips to said jaws in a predetermined path for insertion of one of the clips therebetween while said jaws are in said open position so as to become cinched when said jaws move to said closed position; and mounting means mounting at least part of said supply means for angular displacement about said path so as to vary the orientation at which said clip is presented to said site, said mounting means comprising a handle, an elongate hollow barrel having a longitudinal axis and being mounted in said handle for turning movement relative thereto about said axis, said barrel having an extension of circular cross section at least in part located within said handle, and control means operative at the option of a user for effecting said angular displacement of said barrel, said control means comprising cooperating motion-transmitting portions respectively on said barrel and on a slide member mounted for translatory movement to and fro relative to said handle and lengthwise of said longitudinal axis, said instrument being capable of single hand actuation of said jaws and said angular displacement.

It is currently preferred to mount the assembly composed of the jaws, the entire magazine, i.e., the clip supply means, and the barrel in such a manner that they can all rotate about the longitudinal axis of the instrument, which is also about the path of movement of clips. Further, in one embodiment, the slide member, in the form of a switch or button is slidable lengthwise of this path by finger pressure and, in so doing, effects turning, i.e., angular displacement of the assembly, in one or in the opposite direction. It is then a simple

Ĺ

20

35

matter for the surgeon, using the same hand as that for actuation of the jaws, to change the presentation (orientation) of the leading clip relative to the surgical site merely by pushing the slide button further forwards or backwards and without having to alter the position of his hand relative to the surgical site. The possibility of undue fatigue resulting from the need to hold the instrument in what is to the surgeon an uncomfortable or inconvenient position is thereby avoided.

An ancillary feature in this invention is to operatively connect a trigger to at least the supply means to effect operation thereof.

The novel features which are considered to be characteristic of the invention are set forth in particular in the appended claims. The improved device itself, however, together with its construction and mode of operation, as well as additional features and advantages thereof, will be best understood upon a perusal of the following detailed description of a specific, although purely exemplary, embodiment with reference to the accompanying drawing.

Fig. 1 is a top view, illustrating a prior art instrument known from U.S. Patent No. 4.296.751:

Fig. 2 is a side elevational view, partly in vertical section, illustrating one embodiment of the invention;

Fig. 3 is an exploded perspective view of the embodiment of Fig. 2; and

Fig. 4 is a fragmental top plan view of the embodiment of Fig. 2.

An exemplary embodiment of the invention is illustrated in Figs. 2—4, which will be described hereinafter. It should be emphasized that no particular details are either illustrated or described as to the clip magazine, the clip feed mecahnism or the like, since these are already known per se from U.S. Patent No. 4,296,751, from which all such details may be readily obtained. The description and illustration herein are directed strictly to the novel aspects of the present invention; however, to establish a general overview, Fig. 1 has been included.

To establish the differences and similarities between the invention and the device of U.S. Patent No. 4,296,751, the patented device will first be described.

The device in Fig. 1 is constructed as a hemostat forceps and identified in toto with reference numeral 1. It has two arms 2,4 which are pivotally connected by means of a pivot on one and a cooperating transverse slot 8 in the other arm. The arm 4 is also provided with a pair of transversely spaced clip-cartridge retaining and stabilizing stops 9 and with a hole 26 which receives a pivot of the cartridge 50 containing a string of surgical clips 36 which are tracked by a clip retractor 48.

Arms 2,4 have respective handles 10,12, unlike the present invention which utilizes a trigger type mechanism as will be described in detail later on. The handles 10,12 are separate elements pivoted to the arms 2,4 at pivots 14. In addition, each handle 10,12 is connected at the associated arm 2 or 4 via a slot-and-pin connection 16, of which one is shown in detail in Fig. 1. The connection of the pivot and cooperating slot 8 and the connection 16 provides for a lost-motion movement to permit clip retraction when the arms 2,4 are pivoted relative to one another. Subsequently, the end sections 30 of their curved jaws 28 approach one another.

Handles 10,12 are connected by a link 18 having its two bars pivoted to each other at 20 and the opposite sides of handles 10,12 at 22. A torsion spring 24 has two legs 25 connected to the pivots 22 and thus permanently tends to urge the arms 2,4 apart to the Fig. 1 position. Handles 10 and 12 are also urged to the open position.

It will be seen from Figs. 2—4 that one embodiment of the instrument according to the invention is designated in toto by reference numeral 100. It has a casing formed as a handle composed of two shell sections 102 and 104 (compare Figs. 2 and 3) which are suitably connected, in any manner known per se, to surround the internal mechanism.

That mechanism includes a trigger 106 having stub pivots 108 which are turnably received in mating recesses 110 of shell sections 102 and 104, so that tripper 106 can be angularly displaced about the pivots 108. At least one toggle link 112 is articulated at one end to the trigger 106 by pin 114 which fits into hole 116 in link 112 and holes 118 in trigger 106, and at the other end to a coupling member 120 via a connecting pin 122 which fits into holes 124 of coupling member 120 and hole 126 of link 112. Coupling member 120 is in turn connected via circlip 128 and cooperative groove 130 with an actuating bar or center slide 132. It is important to note that the rear portion 134 of slide 132 is of circular cross section so that it can turn in the recess 136 of coupling member 120, it will be appreciated that coupling member 120 cannot turn because of the presence of connecting pin 122 and link 112. A helical spring 138 surronds rear portion 134 in part and bears against abutments 139 formed on shell sections 102,104 and upon abutments 140 formed on rear portion 134.

The instrument further includes a housing or barrel 142 that accomodates the (not illustrated) clip magazine and feeding mechanism, which together constitute the supply means for the clips. Also accomodated in barrel 142, with only their anvils 144 showing, are the jaws 146 which move between an open and a closed position in which the anvils cinch the respectively leading clip between them. These elements are contained in barrel 142 which is rotatable about its own longitudinal axis, as indicated by the double-headed arrow A. Slide 132 extends into the open rear end of barrel 142 and on into the (not illustrated) cartridge housing where it cooperates in advancing the string of not-illustrated clips towards anvils 144 when the next clip is being inserted between anvils 144 and thereafter retracting all

but the leading clip so that jaws 146 can close and cause anvils 144 to cinch the leading clip between them. For this purpose, slide 132 must also be able to reciprocate lengthwise, which it does every time trigger 106 is pulled and released again.

The clips in the magazine are inserted seriatim between anvils 144 of jaws 146. The respectively leading clip (between anvils 144) is then moved into position by the surgeon by holding the tip of the instrument, i.e., where anvils 144 are located, at or near the surgical site. If it is awkward and/or tiring and/or otherwise bothersome for the surgeon to hold the instrument, and thus his hand, in the position best suited to properly apply the leading clip, the invention now makes it possible to change this so-called "presentation" of the clip relative to the surgical site by turning barrel 142, and thereby anvils 144 and the leading clip held between them, in one of the other of the directions indicated by arrow A.

The surgeon must be able to make this change in presentation simply, rapidly and without any real effort if he is to be assisted and relieved in his work by the present invention. Accordingly, the invention makes it possible for him to turn barrel 142 simply by sliding a switch or button 148 forwards or backwards with a finger or thumb of one hand, the backwards or forwards motion being dependent upon whether it is desired to turn barrel 142 in one or in the other direction indicated by arrow A. The edges of switch 148 slide on recessed flanges 150 of a cutout defined by the two shell sections 102,104 and switch 148 is provided, at its underside in the illustrated embodiment, with a connected portion 152 which may be of any desired shape such as spherical. Portion 152 extends into a groove 154 of the rearward extension 156 of barrel 142. The groove 154 extends lengthwise of extension 156 of barrel 142; in addition, however, it also extends circumferentially of extension 156, which is of circular cross section. Consequently, since switch 148 is constrained to perform a linear movement along flanges 150, the portion 152 travelling in groove 154 of extension 156 imposes a turning movement (see arrow A) upon barrel 142 and extension 156. This, then, also changes the presentation (orientation) of anvils 144, and the leading clip held between them, relative to the surgical site without the surgeon having to change the position of his hand.

It is self-evident that this mechanical way of changing the presentation of the leading clip relative to the surgical site can save the surgeon much awkwardness and fatigue, enabling him to perform his task more quickly and accurately. It is further clear that various modifications may be made in the illustrated instrument.

#### Claims

1. A surgical instrument (100) for applying clips to a surgical site, comprising applicator means having a pair of cooperating jaws (146) which are

movable between an open and a closed position; supply means for feeding surgical clips to said jaws in a predetermined path for insertion of one of the clips therebetween while said jaws are in said open position so as to become cinched when said jaws move to said closed position; and mounting means mounting at least part of said supply means for angular displacement about said path so as to vary the orientation at which said clip is presented to said site, said mounting means comprising a handle (102,104), an elongate hollow barrel (142) having a longitudinal axis and being mounted in said handle for turning movement relative thereto about said axis, said barrel having an extension (156) of circular cross section at least in part located within said handle, and control means operative at the option of a user for effecting said angular displacement of said barrel, said control means comprising cooperating motion-transmitting portions (154,152) respectively on said barrel and on a slide member (148) mounted for translatory movement to and fro relative to said handle and lengthwise of said longitudinal axis, said instrument being capable of single hand actuation of said jaws and said angular displacement.

2. A surgical instrument according to claim 1, the elongate hollow barrel at least in part accommodating said supply means, said barrel having a leading end and a trailing end, said trailing end being provided with said extension of circular cross section, said mounting means further including a groove formed in said extension and extending lengthwise and also circumferentially of said axis, and the motion-transmitting portion of the slide member being a connecting portion riding in said groove so that translatory sliding of said slide member lengthwise of said axis is converted into turning movement of said barrel about said axis.

3. A surgical instrument according to claim 1 or 2, wherein the slide member is slidable in a slot extending lengthwise of the handle.

4. A surgical instrument according to claim 3, wherein the handle has a cutout constituting said slot and extending along said axis, the cutout being flanked by respective edge portions and the slide member having lateral marginal portions which rest and slide upon said edge portions.

5. A surgical instrument according to any preceding claim, wherein a trigger member is connected to the handle for displacement relative thereto and is connected to said supply means to effect operation thereof.

6. A surgical instrument according to claim 5, wherein the trigger is displaceable relative to the handle about a pivot axis which extends crosswise of said longitudinal axis.

7. A surgical instrument according to claim 5 or 6, wherein the trigger member has an axis at an obtuse angle to said path.

8. A surgical instrument according to any preceding claim, wherein said supply means feeds a string of said clips and the instrument includes means associated with said supply means for

65

50

55

20

35

ΔΩ

retracting all except the respective leading clip of said string of clips in a direction away from said jaws prior to said leading clip being completely cinched.

 A surgical instrument according to any preceding claim, wherein at least the jaws of the applicator means are mounted for angular displacement with the barrel.

#### Patentansprüche

- 1. Ein chirurgisches Instrument (100) zum Anbringen von Klammern auf einer Operationsfläche, gekennzeichnet durch eine Appliziervorrichtung die ein Paar von zusammenwirkenden Klemmbacken (146) aufweist, die zwischen einer offenen und geschlossenen Stellung bewegbar sind, durch eine Zuführvorrichtung zur Zuführung chirurgischer Klammern zu den Klemmbakken auf einem vorgegebenen Weg zum Einsetzen einer der Klammern zwischen die beiden Klemmbacken in der geöffneten Stellung, so daß sie zusammengezogen wird, wenn sich die Backen schließen und durch ein Gestell, das zumindest einen Teil der Zuführvorrichtung festhält, damit diese um die Längsachse des Zuführwegs winkelverdreht werden kann, um so die Ausrichtung der Klammern auf der Operationsfläche beliebig verändern zu können, wobei das Gestell folgende Teile aufweist: einen Griff (102,104), einen länglichen, hohlen Zylinder (142), der eine Längsachse aufweist und im Griff befestigt ist, um relativ hierzu um die Achse drehbar zu sein, und der eine Verlängerung (156), besitzt, die einen Rundquerschnitt aufweist und zumindest zum Teil im Griff untergebracht ist, und eine Kontrollvorrichtung die nach Belieben eines Benutzers betätigbar ist, um die Winkeldrehung des Zylinders auszuführen, wobei diese Kontrollvorrichtung zusammenwirkende Teile (154,152) aufweist zur jeweiligen Bewegungsübertragung auf den Zylinder und auf ein Gleitelement (148), das für eine Schubbewegung hin- und her relativ zum Griff und in Längsrichtung entsprechend der Längsachse ausgebildet ist, wobei das Instrument zur Betätigung der Klemmbacken und zur Winkeldrehung einhändig bedienbar ist.
- 2. Ein chirurgisches Instrument nach Anspruch 1, dadurch gekennzeichnet, daß der längliche, hohle Zylinder die Zuführeinrichtung zumindest teilweise aufnimmt und der Zylinder ein Führungsende und ein hinteres Ende aufweist, wobei das hintere Ende die Verlängerung mit Rundquerschnitt aufweist, das Gastell desweiteren in der Verlängerung eine Nut einschließt, die sich in Längsrichtung und um dem Umfang der Achse erstreckt, und das bewegungübertragende Teil des Gleitelementes als ein Verbindungselement ausgebildet ist, das in der Nut läuft, so daß die gleitende Schubbewegung das Gleitelementes in Längsrichtung zur Achse in eine Drehbewegung des Zylinders um die Achse umgewandelt wird.

3. Ein chirurgisches Instrument nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Gleitelement in einem Schlitz gleitbar ist, der sich in Längsrichtung zum Griff erstreckt.

4. Ein chirurgisches Instrument nach Anspruch 3, dadurch gekennzeichnet, daß der Griff eine Aussparung besitzt, die den Schlitz darstellt, und sich entlang der Achse erstreckt, wobei die Aussparung jeweils seitlich von Kantenabschnitten begrenzt ist und das Gleitelement seitliche Randabschnitte aufweist, die auf den Kantanabschnitten liegen und sich auf diesen gleitend bewegen.

5. Ein chirurgisches Instrument nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, daß ein Auslöseelement relativ zu dem Griff bewegbar mit diesem und mit der Zuführvorrichtung zwecks Betätigung derselben verbunden ist.

6. Ein chirurgisches Instrument nach Anspruch 5, dadurch gekennzeichnet, daß der Auslöser auf einer Gelenkachse relativ zum Griff bewegbar ist, die sich quer zur Längsachse erstreckt.

7. Ein chirurgisches Instrument nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß das Auslöseelement eine Achse im stumpfen Winkel zum Zuführweg aufweist.

8. Ein chirurgisches Instrument nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, daß die Zuführvorrichtung eine Reihe von Klammen zuführt und das Instrument eine Vorrichtung besitzt, die der Zuführvorrichtung zugeordnet ist, um außer der ersten Klammer der Reihe alle Klammern in Richtung weg von den Klemmbacken zurückzuziehen, bevor die erste Klammer völlig zusammengezogen wird.

9. Ein chirurgisches Instrument nach einem der vorgenannten Ansprüche, dadurch gekennzeichnet, daß zumindest die Klemmbacken der Appliziervorrichtung zur Winkeldrehung mit dem Zylinder ausgebildet sind.

### Revendications

1. Instrument chirurgical (100) pour appliquer des clips à un champ opératoire, comprenant un moyen d'application possédant une paire de mâchoires coopérantes (146) qui sont mobiles entre une position ouverte et une position fermée; un moyen d'alimentation pour alimenter lesdites mâchoires en clips chirurgicaux dans une trajectoire prédéterminée, pour insérer un clip entre lesdites mâchoires pendant que cellesci sont dans ladite position ouverte, de façon à être fermé lorsque lesdites mâchoires passent dans ladite position fermée; un moyen de montage montant au moins une partie dudit moyen d'alimentation en vue d'un déplacement angulaire autour de ladite trajectoire, de façon à varier l'orientation dans laquelle ledit clip est présenté audit champ, ledit moyen de montage comprenant une poignée (102, 104), un barillet creux allongé (142) ayant un axe longitudinal et monté dans ladite poignée en vue d'un mouvement tournant relativement à celle-ci autour dudit axe, ledit barillet ayant un prolongement (156), de section transversale circulaire, situé au moins en partie à l'intérieur de ladite poignée, et un moyen de contrôle manipulable selon le choix d'un utili-

65

55

15

25

sateur pour effectuer ledit déplacement angulaire dudit barillet, ledit moyen de contrôle comprenant des parties (154, 152) transmettrices de mouvement coopérantes, respectivement sur ledit barillet et sur une pièce coulissante (148), montée pour se déplacer en un mouvement de translation aller et retour relativement à ladite poignée et le long dudit axe longitudinal, ledit instrument permettant d'actionner d'une seule main lesdites mâchoires et ledit déplacement angulaire.

2. Instrument chirurgical selon la revendication 1, le barrliet creux allongé logeant au moins en partie ledit moyen d'alimentation, ledit barillet possédant une extrémité de tête et une extrémité arrière, ladite extrémité arrière étant pourvue dudit prolongement de section transversale circulaire, ledit moyen de montage comprenant de plus une rainure formée dans ledit prolongement et s'étendant dans le sens de la longueur et également selon la circonférence dudit axe, et la partie de la pièce coulissante transmettant le mouvement étant une partie de connexion se déplaçant dans ladite rainure de teile manière que le glissement de translation de ladite pièce coulissante dans le sens de la longueur dudit axe est converti en un mouvement de rotation dudit barillet autour dudit axe.

3. Instrument chirurgical selon la revendication 1 ou 2, où la pièce coulissante peut glisser dans une fente s'étendant dans le sens de la longueur de la poignée.

Instrument chirurgical selon la revendication
 ou la poignée a une découpe constituant ladite

fente et s'étendant le long dudit axe, la découpe étant flanquée par des rebords respectifs et la pièce coulissante possédant des parties marginales latérales qui reposent et glissent sur lesdits rebords.

5. Instrument chirurgical selon l'une quelconque des revendications précédentes, où une gâchette est reliée à la poignée en vue d'un déplacement relatif vers celle-ci et est reliée audit moyen d'alimentation pour en effectuer la manoeuvre.

6. Instrument chirurgical selon la revendication 5, où la gâchette peut être déplacée relativement à la poignée autour d'un axe-pivot qui se prolonge transversalement par rapport audit axe longitudinal.

7. Instrument chirurgical selon la revendication 5 où 6, ou la gâchette a un axe faisant un angle obtu avec ladite trajectoire.

8. Instrument chirurgical selon l'une quelconque des revendications précédentes, où ledit moyen d'alimentation alimente un cordon desdits clips et où l'instrument comporte un moyen associé audit moyen d'alimentation pour faire reculer tous les clips dudit cordon, excepté le cilp de tête, dans une direction s'écartant desdites mâchoires avant que ledit clip de tête soit complètement fermé.

9. Instrument chirurgical selon l'une quelconque des revendications précédentes, où au moins les mâchoires du moyen d'application sont montées en vue d'un déplacement angulaire avec le barillet.

35

30

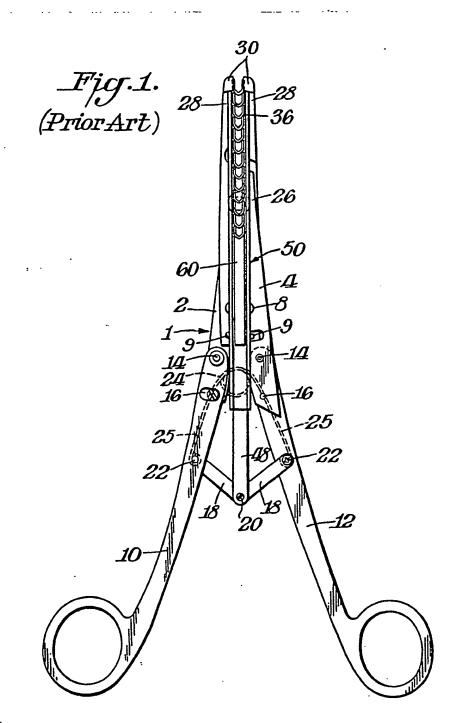
40

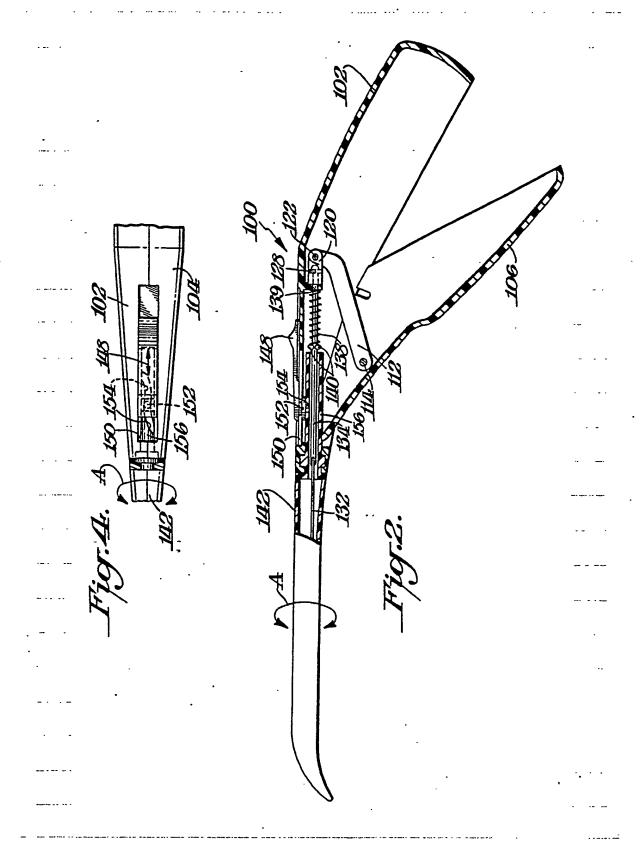
45

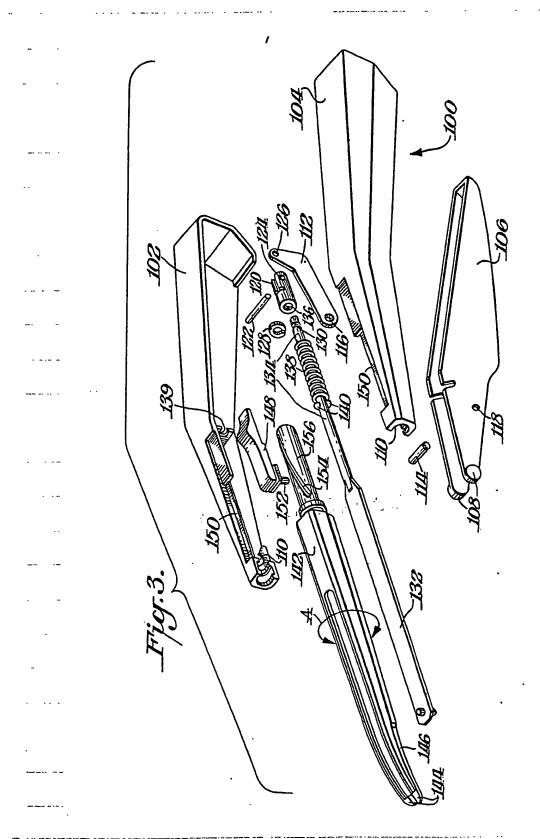
50

55

60







THIS PAGE BLANK (USPTO)